IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT BLUEFIELD

UNITED STATES OF AMERICA,

Plaintiff,

v. CIVIL ACTION NO. 1:22-00458

SOUL VAPOR, LLC,
and AURELIUS JEFFREY

Defendants.

MEMORANDUM OPINION

On September 29, 2023, the court entered an order granting plaintiff's motion for summary judgment. On May 8, 2024, the court held a hearing on plaintiff's proposed injunction and defendants' objections thereto. The court declines to enter the government's proposed injunction in its entirety. The reasons for those decisions follow.

I. Background

The Tobacco Control Act ("TCA") authorizes the United States Food & Drug Administration ("FDA") "to regulate tobacco products including 'cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco,' as well as 'any other tobacco products that the [FDA] by regulation deems to be subject' to the TCA." Avail Vapor, LLC v. FDA, 55 F.4th 409, 414 (4th Cir. 2022). "Electronic nicotine delivery systems (ENDS), also known as e-cigarettes, were introduced widely in the United States

after Congress passed the TCA. In contrast to traditional cigarettes, ENDS heat a liquid that includes nicotine, chemicals, and flavors until it generates an aerosol or vapor, which can then be inhaled by the user." Id. (citing Nicopure Labs, LLC v. FDA, 944 F.3d 267, 270 (D.C. Cir. 2019)); see also Nicopure Labs, LLC v. FDA, 266 F. Supp.3d 360, 366 (D.D.C. 2017) ("An electronic cigarette, or 'e-cigarette,' is an electronic nicotine delivery device, comprised of a liquid, an atomizer or heating element that heats the liquid to create a vapor, and a battery that powers the heating element."). In 2016, the FDA asserted regulatory jurisdiction over ENDS products. See id. at 415. In this case, the FDA claims that defendants' manufacture, sale, and marketing of ENDS products violates the Food, Drug and Cosmetics Act ("FDCA" or "the Act").

A.

Soul Vapor, LLC ("Soul Vapor") is a West Virginia corporation located in Princeton, West Virginia. See Complaint ¶ 1; Defendants' Answer ¶ 4 (ECF No. 6). Aurelius Jeffrey is "the principal and responsible party" for Soul Vapor. Declaration of Aurelius Jeffrey (hereinafter "Jeffrey Decl. at ¶ ___") at ¶ 1. Jeffrey "opened Soul Vapor as an online store in 2015, offering [a] house line of open tank e-liquids (all of which included nicotine)." Id. at ¶ 2. In 2019, Jeffrey opened a brick-and-mortar store located at 604 Thorn Street in

Princeton. See id. Soul Vapor was registered as an LLC with the State of West Virginia in early 2021. See id.

B.

The Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, ("the Act") imposes restrictions on the manufacture, sale, and marketing of tobacco products. See Declaration of Elenita Ibarra-Pratt (hereinafter "Ibarra-Pratt Decl. at ¶ ___") at ¶ 3. The Act defines "tobacco product" as "any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product." 21 U.S.C. § 321(rr); see also Ibarra-Pratt Decl. at ¶ 9. ENDS products are "tobacco products" under the Act. See Ibarra-Pratt Decl. at ¶ 10. E-liquids, like those sold by defendants, are ENDS products. See id. at ¶ 10 ("E-liquids are a type of ENDS product and generally refer to liquid nicotine and nicotine-containing e-liquids[.]") (internal quotation and citation omitted); see also Declaration of Matthew McNew (hereinafter "McNew Decl. at ¶ ___") at ¶ 9.

The Act requires "every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products" to register with the FDA "the name, places of business, and all such establishments of that person." 21

U.S.C. § 387e(b); Ibarra-Pratt Decl. at ¶ 13. In addition, "every person who registers with FDA must, at the time of registration, file a list of all tobacco products manufactured, prepared, compounded, or processed by that person for commercial distribution, and biannually update such list thereafter." Ibarra-Pratt Decl. at ¶ 13 (citing 21 U.S.C. § 387e(i)).

In addition, all new tobacco products must have FDA authorization prior to their marketing. See 21 U.S.C. § 387j(a)(2)(A); Ibarra-Pratt Decl. at ¶ 12. The Act defines "new tobacco product" to include "any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007." 21 U.S.C. § 387j(a)(1). The FDA maintains "a public database of tobacco products that FDA has determined were commercially marketed in the United States as of February 15, 2007, and therefore are 'pre-existing' tobacco products." Ibarra-Pratt Decl. at ¶ 17.

A new tobacco product may receive FDA marketing authorization through any of three pathways: (1) the premarket tobacco product application ("PMTA") pathway under 21 U.S.C. § 387j, through which FDA reviews a PMTA and issues a marketing granted order for the new tobacco product ("MGO") under 21 U.S.C. § 387j(c)(1)(A)(i) upon a finding that the product is appropriate for the protection of the public health; (2) the substantial equivalence ("SE") pathway under 21 U.S.C. §

387j(a)(2)(A)(i), through which FDA reviews a report submitted under 21 U.S.C. § 387e(j) ("SE report") for the product and issues an order determining, among other things, that it is substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, or a tobacco product marketed after that date, but which FDA previously determined to be substantially equivalent ("SE order"); or (3) the SE exemption pathway under 21 U.S.C. § 387j(a)(2)(A)(ii), through which FDA reviews an exemption request submitted under 21 C.F.R. § 1107.1 and a report submitted under 21 U.S.C. § 387e(j)(1) ("abbreviated report") for the product, and issues a "found-exempt" order pursuant to 21 U.S.C. § 387e(j)(3)(A). Nicopure, 266 F.3d at 372-73; Ibarra-Pratt Decl. at ¶ 12; ECF 11-1.

The FDA's Office of Compliance and Enforcement ("OCE")[1] is charged with implementing and enforcing the Act and its implementing regulations." Ibarra-Pratt Decl. at ¶ 3. OCE "monitor[s] retailer, manufacturer, importer, and distributor compliance with the Act and its implementing regulations" and is responsible for "taking corrective action as appropriate[.]" Id. Such action may include sending a Warning Letter to a non-compliant entity, recommending an enforcement action seeking

[1] The OCE is a part of the FDA's Center for Tobacco Products ("CTP"). See Declaration of Nathan Everly (hereinafter "Everly Decl. at ¶ ___") at ¶ 1.

injunctive relief and civil monetary penalties, or recommending criminal prosecution. See Ibarra-Pratt Decl. at ¶ 25.

C.

On March 21, 2021, OCE conducted a review of Soul Vapor's website. See Ibarra-Pratt Decl. at ¶ 26. "OCE observed that the website represented that Soul Vapor manufactures ENDS products, including Soul Vapor Honey Pot and Soul Vapor Peach Rings, and offers them for sale or distribution to consumers in the United States. OCE also documented that the Soul Vapor website is registered to [Soul Vapor and Jeffrey] and that FDA has not issued any marketing authorization orders for Soul Vapor Honey Pot or Soul Vapor Peach Rings." Ibarra-Pratt Decl. at ¶ 26.

In response to the problems noted in its review of Soul Vapor's website, FDA sent Soul Vapor a Warning Letter on May 21, 2021. See Ibarra-Pratt Decl. at ¶ 27; see also ECF No. 11-1 (Warning Letter). The Warning Letter was sent to Jeffrey's attention and explained its concerns about Soul Vapor's operations. Specifically, the letter explained:

> The Center for Tobacco Products of the U.S. Food and Drug Administration (FDA) recently reviewed the website https://www.soulvaporejuice.com and determined that the e-liquid products listed there are manufactured and offered for sale or distribution to customers in the United States.
>
> Under section 201(rr) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(rr)), these

products are tobacco products because they are made or derived from tobacco and intended for human consumption. Certain tobacco products, including e-liquids, are subject to FDA jurisdiction under section 901(b) of the FD&C Act (21 U.S.C. § 387a(b)) and 21 C.F.R. § 1100.1. Therefore, e-liquids are required to be in compliance with the requirements in the FD&C Act.

Please be aware that, effective August 8, 2016, FDA deemed additional products meeting the definition of a tobacco product, except accessories to these newly deemed products, to be subject to regulation under the FD&C Act. These products include, but are not limited to, ENDS (including e-cigarettes and e-liquids), cigars, and pipe tobacco. See Final Rule, Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974 (May 10, 2016), available at https://federalregister.gov/a/2016-10685.

Generally, to be legally marketed in the United States, the FD&C Act requires "new tobacco products" to have a premarket authorization order in effect. A "new tobacco product" is any tobacco product that was not commercially marketed in the United States as of February 15, 2007, or any modified tobacco product that was commercially marketed after February 15, 2007 (section 910(a) of the FD&C Act; 21 U.S.C. § 387j(a)). Generally, a marketing authorization order under section 910(c)(1)(A)(i) of the FD&C Act (21 U.S.C. § 387j(c)(1)(A)(i)) is required for a new tobacco product unless (1) the manufacturer of the product submitted a report under section 905(j) of the FD&C Act (21 U.S.C. § 387e(j)) and FDA issues an order finding the production substantially equivalent to a predicate tobacco product (section 910(a)(2)(A) of the FD&C Act) or (2) the manufacturer submitted a report under section 905(j)(1)(A)(ii) of the FD&C Act (21 U.S.C. § 387e(j)(1)(A)(ii)) and all modifications are covered by exemptions from the requirements of substantial equivalence granted by FDA under section 905(j)(3) of the FD&C Act (21 U.S.C. § 387e(j)(3)).

New Tobacco Products Without Required Marketing Authorization are Adulterated and Misbranded

Our review of https://www.soulvaporejuice.com revealed that you manufacture and offer for sale or distribution to customers in the United States e-liquid products without a marketing authorization order including: Soul Vapor Honey Pot and Soul Vapor Peach Rings.

The e-liquid listed above are new tobacco products because they were not commercially marketed in the United States as of February 15, 2007. These products do not have an FDA marketing authorization order in effect under section 91(c)(1)(A)(i) of the FD&C Act and are not otherwise exempt from the marketing authorization requirement. Therefore, these products are adulterated under section 902(6)(A) of the FD&C Act. In addition, these products are misbranded under section 903(a)(6) of the FD&C Act because a notice or other information respecting these products was not provided as required by section 905(j) of the FD&C Act.

Conclusion and Requested Actions

Your firm is a registered manufacturer with over 2,100 products listed with FDA. It is your responsibility to ensure that your tobacco products and all related labeling and/or advertising on this website, on any other websites (including e-commerce, social networking, or search engine websites), in any other media in which you advertise, and in any retail establishments comply with each applicable provision of the FD&C Act and FDA's implementing regulations. Failure to address any violations of the FD&C Act, 21 U.S.C. § 301 et seq., Chapter IX, relating to tobacco products including the tobacco regulations in 21 C.F.R. Parts 1140, 1141, and 1143, may lead to regulatory action, including, but not limited to, civil money penalties, seizure, and/or injunction. . . .

The violations discussed in this letter do not necessarily constitute an exhaustive list. You should address any violations that are referenced above, as well as any violations that are the same as or similar

> to those stated above, and promptly take any necessary actions to bring your tobacco products into compliance with the FD&C Act.

ECF No. 11-1; Ibarra-Pratt Decl. at ¶ 27. The Warning Letter went on to ask Jeffrey to provide a "written response" to the letter describing "actions to address any violations and bring your products into compliance, including the dates on which you discontinued the violative labeling, advertising, sale, and/or distribution of these tobacco products and your plan for maintaining compliance with the FD&C Act." ECF No. 11-1. The Warning Letter invited Jeffrey to provide "reasoning and any supporting information" if he believed that his products did not violate the Act. Id.

As a follow-up to the Warning Letter, on June 4, 2021, Nick Miletech with OCE emailed Jeffrey to schedule a call to discuss the Warning Letter. See ECF No. 26-2. Jeffrey responded to Miletech's email with his availability later that same day. See id. Ultimately, a telephone conference was scheduled for June 8, 2021. See id.

Nathan Everly, a Supervisory Consumer Safety Officer in the OCE, participated in the telephone conference with Jeffrey on June 8, 2021. See Declaration of Nathan Everly (hereinafter "Everly Decl. at ¶ ___") at ¶ 5. Everly "was the highest-ranking CTP/OCE official on the call, and [ ] did most of the talking to Mr. Jeffrey during the call." Id. During the call,

Jeffrey confirmed that he was the owner of Soul Vapor and that the company manufactures and sells ENDS products. See id. at ¶ 6. Everly asked "Jeffrey to summarize Soul Vapor's corrective actions in response to the May 21, 2021 Warning Letter." See id. at ¶ 7. In response, Jeffrey said "he intended to submit premarket tobacco product applications ("PMTAs") for Soul Vapor-brand ENDS products, and that he would discontinue manufacturing and selling such products and place all inventory of such products in storage until they receive FDA authorization." See id. at ¶ 8. Jeffrey further indicated that he would disable the checkout process for the Soul Vapor website to prevent online purchases. See id. at ¶ 9. Jeffrey asked about the PMTA process and Everly directed him to the FDA website to find out more information. See id. at ¶¶ 11, 12.

Jeffrey's account of the teleconference on June 8, 2021, is largely consistent with Everly's. He maintains that he asked OCE if he should remove the information from the website "regarding Soul Vapor's e-liquid products then shown on the website completely, or if removing the payment gateway was sufficient so that no purchases could be made. The FDA representative stated that it was sufficient to remove the payment gateway." Jeffrey Decl. at ¶ 4. Jeffrey followed up the teleconference with an email to OCE memorializing the meeting. See id. at ¶ 5. Specifically, Jeffrey wrote:

> I am writing you in regards to a warning letter we received on May 21st for our company Soul Vapor. I just spoke with your office today regarding the letter and am writing to let you know what our plan of action is. I will have our team work on having the payment gateway removed from our website, soulvaporejuice.com, by the end of the week. As for the product in our vape shop, I will have the product removed from our shelves and put [it in] our stock room by the end of the week as well. Now that I have some clarification on the PMTA process itself I will work on filing our products with the FDA as soon as possible. I will read up on the FDA website and contact you if I have any questions. Thank you for your time during the conference call.

ECF No. 26-2; Ibarra-Pratt Decl. at ¶ 28.

According to Jeffrey, he did what he said he would do in the email. Jeffrey Decl. at ¶ 6. He removed the payment gateway from the website and moved all the nicotine e-liquids from display and put them in storage. See id. Jeffrey stated that his interactions with FDA caused him to make changes to his business model. See id. at ¶ 7. "From that point on, I changed Soul Vapor's operations. Instead of making e-liquids with nicotine, we began preparing mixtures of PG/VG and various flavors, but without nicotine included in the mixture. Instead, we sold nicotine in separate containers for customers desiring nicotine." Id. According to Jeffrey, "[n]ot all customers use nicotine; approximately five percent of our customers vape solely the PG/VG/flavor mixture without nicotine." Id.

D.

After OCE "observ[ed] that Soul Vapor's website still offered for sale or distribution ENDS products that lacked FDA marketing authorization[,]" another teleconference between OCE and Jeffrey was arranged for July 20, 2021. Ibarra-Pratt Decl. at ¶ 29. Jeffrey was "surprised" by the request for another meeting because he believed that he had done everything that FDA wanted. See Jeffrey Decl. at ¶ 8.

On July 20, 2021, OCE held a second teleconference with Jeffrey. See Everly Decl. at ¶ 14. Once again, Everly was the highest-ranking CTP/OCE official on the call and did most of the talking. See id. Everly notified Jeffrey that FDA had observed the Soul Vapor website still offered for sale new tobacco products that lacked the required FDA authorization. See id. at ¶ 15. Jeffrey "responded that he would modify the Soul Vapor website to state that Soul Vapor-brand ENDS products are no longer for sale, and that he would complete this action by July 21, 2021." See id. at ¶ 16. Everly ended the call by telling Jeffrey that "CTP would evaluate the corrective action proposed by Mr. Jeffrey during the call and in any subsequent written response." See id. at ¶ 17.

Jeffrey takes issue with Everly's account of their teleconference on July 20, 2021. See Jeffrey Decl. at ¶ 9. According to him, Everly's account is "misleading because it

suggests that [he] had not done something that was specifically requested" and that he felt he had "complied with FDA's requests after the initial call[.]" Id.

Later that same day, Jeffrey followed up on the teleconference of July 20, 2021, by email. See Ibarra-Pratt Decl. at ¶ 29. Jeffrey wrote that "ejuice is no longer being manufactured as [sic] is no longer available for purchase" and that he had "resolved the concerns . . . referenced in both the warning letter and teleconferences." Id.

E.

FDA inspected Soul Vapor's retail establishment on Thorn Street on March 23 and 25, 2022. See McNew Decl. at ¶ 7; see also Ibarra-Pratt Decl. at ¶ 30. Matthew McNew, a Consumer Safety Officer ("CSO") within the Tobacco Operations Staff ("TOS") was the lead investigator during the inspection. See id. at ¶¶ 1, 7. Investigator Young Kim assisted McNew during the inspection. See id. at ¶ 7. During the investigation, McNew documented that "Defendants manufacture, sell, and distribute finished ENDS products, including finished e-liquid products, at and from Defendants' establishment. Defendants' manufacturing activities include mixing, bottling, and labeling their ENDS products." Id. at ¶ 9. Although McNew did not observe defendants manufacturing ENDS products during the inspection, "he observed evidence of ENDS product manufacturing

at Defendants' establishment, including nicotine, flavorings, bottles, labels, and equipment to manufacture ENDS products." Id. at ¶ 11. According to McNew, Jeffrey also told him that "Soul Vapor currently manufactures ENDS products." Id. In describing Soul Vapor's operation, McNew noted:

> During the March 2022 inspection, Mr. Jeffrey stated that Defendants' ENDS product manufacturing includes: bottling bulk liquid nicotine at varying concentrations into 10mL bottles; and, separately, mixing flavoring(s) with propylene glycol ("PG") and vegetable glycerin ("VG"), and packaging the resulting flavoring/PG/VG blend into a 10mL, 30mL, or 120mL bottle. Mr. Jeffrey stated that Defendants do not mix the manufactured liquid nicotine and flavoring/PG/VG blends separately, retail employees of Soul Vapor provide verbal instructions to the customer on properly mixing them.

Id. at ¶ 12. He also observed that Soul Vapor sold finished ENDS products under the Soul Vapor brand as well as finished ENDS products manufactured by others. See id. at ¶ 15.

According to McNew, during a close-out meeting, he reminded Jeffrey of his duty to comply with the Act. See id. at ¶ 18. Jeffrey informed McNew "that he believes that he no longer manufactures finished tobacco products because he no longer mixes liquid nicotine with flavorings or flavoring/PG/VG blends." Id. "Jeffrey further stated that he had not, and did not intend to, submit marketing applications for his liquid nicotine and flavoring/PG/VG blend products." Id.

During that inspection, FDA observed that the corrective measures promised by Jeffrey in this emails of June 8, 2021 and July 20, 2021, had not been implemented. Ibarra-Pratt Decl. at ¶ 30. "Specifically, FDA observed that Defendants continued to manufacture ENDS products, including finished e-liquids under the Soul Vapor brand, that lacked FDA authorization, and offer them for sale on the retail shelves of Defendants' establishment." Ibarra-Pratt Decl. at ¶ 30.

Jeffrey has a different view of his compliance with the Act. Simply put, he does "not believe that Soul Vapor is engaged in activity regulated by the FDA or within FDA jurisdiction after [its] change in operations products" wherein Soul Vapor was selling "nicotine separated from the flavored juice[.]" Jeffrey Decl. at ¶¶ 14 and 15. And he told McNew and Kim as much during their inspection of Soul Vapor. See id. at ¶ 15. According to Jeffrey, McNew "specifically stated multiple times that his superiors said that the way Soul Vapor was selling—with the nicotine separated from the flavored juice—was something they had not seen before and they did not know what to do with my situation." Id. at ¶ 14. Jeffrey stated:

> At the conclusion of the inspection, I had a meeting with the inspectors. Mr. New [sic], referring to Soul Vapor's new method of selling, i.e., separating the nicotine from the PG/VG/flavor products, said "you're the first person we've seen do this, so there's no preceden[t] for how to handle your situation."

> He noted that "any minor changes we've requested you've done, so I don't see any issues." He said that he did not have any more suggestions or requests. New [sic] also stated that "you're not directly violating any rules" and therefore he would not issue a notice of any violation. Neither he nor Kim ever stated that what I was doing was prohibited.
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> * * *
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> At the conclusion of the inspection, I believed that it had ended on good terms and that the matter had been resolved, especially given that Mr. New [sic] told me he observed no violations after three days.
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> * * *
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> In September 2021, I logged into the FDA's registration system to update our status based on our changed operations and product offerings. From what I recall, the only options are stating that you are in business or out of business. I designated Soul Vapor as inactive, because we are not active in a way captured by the law or FDA regulations, which only extend to tobacco product manufacturers/processors as defined in the statute. At this point we are just a vape shop that is not engaged in manufacturing regulated products.

Jeffrey Decl. at ¶¶ 16, 18-19.

F.

By letter dated August 31, 2022, the Department of Justice ("DOJ") sent a letter to Soul Vapor and Jeffrey advising them that the FDA had determined they were in violation of the Food, Drug, and Cosmetic Act and that the government was prepared to seek a permanent injunction to prevent further violations of the Act. See ECF No. 26-5. The DOJ's letter included a proposed consent decree that would settle the matter. See id. The

letter gave Soul Vapor and Jeffrey until September 8, 2022, to contact DOJ and warned that failure to respond would result in the government filing a lawsuit against them in federal court. See id.

G.

On October 18, 2022, the United States, on behalf of the FDA, filed its Complaint for Permanent Injunction in this case. See ECF No. 1. Named as defendants were Soul Vapor and Jeffrey. See id. In its complaint, the FDA seeks to permanently enjoin defendants from violating: (1) "21 U.S.C. § 331(k), by causing tobacco products, within the meaning of 21 U.S.C. § 321(rr), to become adulterated and misbranded while they are held for sale after shipment of one or more of their components in interstate commerce;" and (2) "21 U.S.C. § 331(q)(2), by submitting information required by or under the Act respecting a tobacco product that is [ ] false or misleading in any material respect." Id. at ¶ 1.

On February 14, 2023, the United States moved for summary judgment. See ECF Nos. 11 and 12. According to that motion, defendants submitted a required annual registration to FDA with materially false information as follows:

> 12. On September 20, 2021, Defendants submitted an annual registration to FDA wherein they changed the activity status for their Establishment from "active" to "inactive" and reported the reason for the change as the Establishment being "[o]ut of business."

> 13. Between March 23 and 25, 2022, FDA inspected Defendants' Establishment and found that the business was open, active, and engaged in the manufacture and sale of tobacco products.

Id. at ¶¶ 12-13. According to plaintiff's motion, the foregoing was a violation of 21 U.S.C. § 331(q)(2) and they are entitled to summary judgment. Plaintiffs also maintain that there are no disputed issues of material fact that, by causing tobacco products to become adulterated and misbranded while they are held for sale after shipment of one or more of its components in interstate commerce, that defendants had violated 21 U.S.C. § 331(k). Id. at 10-14.

In its opposition to plaintiff's motion for summary judgment, defendant argued that summary judgment should not be granted because defendants did not receive fair notice of the standard of conduct required or there was a disputed issue of material fact as to whether notice sufficient to satisfy due process was provided. Defendants maintain that they should be able to conduct discovery into whether sufficient notice was provided to them and, therefore, summary judgment is premature. Defendants also argue that Soul Vapor's updated registration status with the FDA was not misleading.

II. Legal Standard

"A party may move for summary judgment, identifying each claim or defense—or the part of each claim or defense—on which summary judgment

is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party has the burden of establishing that there is no genuine issue as to any material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). This burden can be met by showing that the nonmoving party has failed to prove an essential element of the nonmoving party's case for which the nonmoving party will bear the burden of proof at trial. Id. at 322. If the moving party meets this burden, according to the United States Supreme Court, "there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Id. at 323.

> Once the moving party has met this burden, the burden shifts to the nonmoving party to produce sufficient evidence for a jury to return a verdict for that party. The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff. The judge's inquiry, therefore, unavoidably asks whether reasonable jurors could find, by a preponderance of the evidence, that the plaintiff is entitled to a verdict . . . .

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." Id. at 250-51.

Federal Rule of Civil Procedure 56(d) provides that "[i]f a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition [to summary judgment], the court may: (1) defer

considering the motion or deny it; (2) allow time to obtain affidavits or declarations or to take discovery; or (3) issue any other appropriate order." A district court's denial of a Rule 56(d) motion is reviewed for abuse of discretion. See Pisano v. Strach, 743 F.3d 927, 931 (4th Cir. 2014). Accordingly, the appeals court will not reverse the denial of a Rule 56(d) motion absent a clear abuse of discretion or a real possibility that the denial of discovery resulted in prejudice to the moving party. See Strag v. Bd. of Trustees., 55 F.3d 943, 954 (4th Cir. 1995).

"[A] court may deny a Rule 56(d) motion when the information sought would not by itself create a genuine issue of material fact sufficient for the nonmovant to survive summary judgment." Pisano, 743 F.3d at 931; see also Poindexter v. Mercedes-Benz Credit Corp., 792 F.3d 406, 411 (4th Cir. 2015) (confirming that to obtain Rule 56(d) relief, the non-moving party bears the burden of showing how discovery "could possibly create a genuine issue of material fact sufficient . . . to survive summary judgment, or otherwise affect the court's analysis") (cleaned up). A "sound reason for denying a Rule 56(d) motion may be that the additional discovery being sought would be futile." Smith v. OSF HealthCare Sys., 933 F.3d 859, 868 (7th Cir. 2019).

III. Discussion

A.

"In response to the Supreme Court's holding that the [FDA] lacked authority under the FDCA to regulate tobacco as a drug, see FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 120 S. Ct. 1291, 146 L.Ed.2d 121 (2000), Congress enacted the Tobacco Control Act to empower the agency to regulate tobacco products." Nicopure Labs, LLC v. FDA, 944 F.3d 267, 272 (D.C. Cir. 2019). Enacted in 2009, the Tobacco Control Act ("TCA") defined a "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." 21 U.S.C. § 321(rr)(1). "Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately covered . . . when the Tobacco Control Act went into effect." "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," 81 Fed. Reg. 28,974 (May 10, 2016) ("Deeming Rule") at 28,975. "For other kinds of tobacco products, the statute

authorizes FDA to issue regulations 'deeming' them to be subject to [the TCA]." Id. at 28,975.

"Sales of e-cigarettes in the United States rose rapidly from 2007 onward." Avail Vapor, 55 F.4th at 415. Because the TCA did not give the FDA immediate jurisdiction over ENDS products, they had "limited regulatory oversight" for a time. Id.

> To close this gap, FDA asserted regulatory jurisdiction over ENDS products in May 2016 in accordance with its authority to "deem" new products subject to the strictures of the TCA. See 21 U.S.C. § 387a(b); 81 Fed. Reg. 28,974 (May 10, 2016) ("Deeming Rule"). It noted that the Deeming Rule was necessary in substantial part due to "the continued dramatic rise in youth and young adult use of tobacco products such as e-cigarettes." Id. at 29,894.

Id. After accepting and reviewing comments, the FDA issued a final rule, effective August 2016, deeming e-cigarettes tobacco products. See Deeming Rule, 81 Fed. Reg. 28,974.[2]

The Deeming Rule did not ban the sale or manufacture of ENDS products, it "simply announced that electronic cigarettes, or electronic nicotine delivery systems ("ENDS") products would be subject to the same set of rules and regulations that

[2]According to the Rule, "[p]roducts that meet the statutory definition of 'tobacco products' include . . . ENDS (including e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes." Deeming Rule, 81 Fed. Reg. at 28,976.

Congress had already put in place for conventional cigarettes." Nicopure, 266 F. Supp.3d at 367.[3]

In the Deeming Rule, "the FDA defined the terms that Congress failed to define in the TCA." Id. at 376. "Component or part" was defined as "any software or assembly of materials intended or reasonably expected: (1) [t]o alter or affect the

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[3] The FDA delayed enforcement of the Deeming Rule for a period of time.

> [T]he FDA also recognized that this new rule meant that most ENDS products were already on the market without manufacturers having submitted a PMTA, a violation of the TCA. Thus, the FDA decided not to act on a product's lack of premarket authorization for two to three years while manufacturers prepared, and FDA reviewed, marketing applications. Id. at 28,977-78. After the Deeming Rule, FDA made a series of public announcements relevant to the matter at hand, which we examine below.
>
> In the summer of 2017, FDA announced that it did not intend to initiate enforcement regarding PMTA for newly regulated ENDS products for five years, i.e., until 2022.

Avail Vapor, 55 F.4th at 415. However, in 2018, in response to what it perceived as a "youth vaping epidemic[,] . . . [t]he FDA began to use its enforcement discretion, issuing over 6,000 warning letters to manufacturers and more than 1,000 civil monetary complaints to retailers for the marketing and sale of ENDS products to minors." Id. at 416 (internal citations omitted).

tobacco product's performance, composition, constituents, or characteristics; or (2) to be used with or for the human consumption of a tobacco product." Deeming Rule, 81 Fed. Reg. at 28,975. Although the Deeming Rule uses "the terms 'component' and 'part' interchangeably and without emphasizing the distinction between the terms[,] it may 'clarify' the distinctions between 'component' and 'part' in the future." Id.

B.

Defendants oppose summary judgment arguing that "the facts reflect a lack of fair notice of the standard of conduct required, or, at a minimum, a material dispute of fact regarding whether notice was provided to satisfy due process." ECF No. 26 at 7. According to them, "[t]he first notice Defendants received that the government considered Soul Vapor's nicotine-free mixtures of PG/VG and flavor to constitute 'new tobacco products' was in the August 31, 2022 DOJ letter." Id. They also characterize this notice as "the government's new apparent reading of the law," arguing that "it directly contradicts the conclusion—following three days of inspections—that no violation was observed." Id. at 7-8 (emphasis in original). Defendants argue that "the government cannot announce a substantive standard of conduct for the first time in an enforcement action." Id. at 8.

The problem with defendants' lack of fair notice argument is that the operative "standard of conduct" was not first announced when the government filed the instant lawsuit. Rather, defendants have been on notice since 2016 that their conduct was prohibited. The 2016 deeming rule provided explicit notice to Soul Vapor and Jeffrey that it could not lawfully market its nicotine-free e-liquid without premarket approval. FDA deemed all "tobacco products (including components and parts but excluding accessories of the newly deemed products) to be subject to the FD&C Act[.]" Deeming Rule, 81 Fed. Reg. at 28,975.

An e-liquid without nicotine can be a "component or part" of a tobacco product under the TCA, and therefore subject to FDA regulation, if it is "intended or reasonably expected to be used with or for the human consumption of a tobacco product." Id. at 29,016; see also id. at 29,017 ("[A]n e-liquid without nicotine is a component (and subject to FDA's tobacco control authorities), if it is intended or reasonably expected to be used with or for the human consumption of a tobacco product (e.g., with liquid nicotine[.]"). In response to a comment "that the [Deeming] rule would create incentives for manufacturers to separate nicotine-containing components from nonnicotine-containing components to evade regulatory requirements," the FDA reiterated that the "deeming rule covers

tobacco products and parts intended or reasonably expected to be used with or for the human consumption of a tobacco product." Id.; see also id. at 29,032 ("Also, as stated earlier, nicotine-free e-liquid that is intended or reasonably expected to be used with or for the human consumption of tobacco products in most cases would be a component or part of a tobacco product and, therefore, within the scope of this rule. These products will be evaluated on a case-by-case basis.").

The Rule goes on to provide that

> In determining whether . . . materials might be "intended or reasonably expected" to alter or affect the tobacco product's performance, composition, constituents, or characteristics or to be used with or for the human consumption of a tobacco product (and, therefore, whether it is a component or part), FDA is not bound by the manufacturer or distributor's subjective claims of intent. Rather, FDA can consider the totality of the circumstances, including direct and circumstantial objective evidence, which encompasses a variety of factors such as the circumstances surrounding the distribution of the product or the context in which it is sold . . . and sales data.

Id. at 29,015.

Defendants' argument has already been rejected by the United States District Court for the District of Columbia in another case. In Nicopure, manufacturers challenged whether the FDA could lawfully regulate nicotine-free e-liquids. See Nicopure, 266 F. Supp.3d at 389. Consistent with the Deeming Rule, the FDA took "the position that it may lawfully regulate

an e-liquid that does not contain nicotine as a 'component' of a tobacco product where the e-liquid 'is intended or reasonably expected to be used with or for the human consumption of a tobacco product (e.g., with liquid nicotine.'" Id. at 390 (quoting Deeming Rule, 81 Fed. Reg. at 29,017). Finding that the FDA's "interpretation [wa]s not inconsistent with the TCA[,]" the court rejected the manufacturers' challenge. Id. at 391. According to the court, "[t]he statutory definition of a regulable 'tobacco product' specifically includes any component of a tobacco product, 21 U.S.C. § 321(rr), and if an ENDS device with nicotine or a tobacco derivative in it is, as plaintiffs acknowledge, a tobacco product, then a nicotine-free liquid that gets added to the mix—to provide flavor or made the inhalation experience less harsh—becomes a 'component' of the tobacco product when it is added." Id.

Based upon the foregoing, defendants' lack of notice argument falls apart. The FDA expressly contemplated defendants' situation, i.e., selling nicotine-free liquids to be mixed with nicotine, and addressed it in the Deeming Rule. And the Deeming Rule notifies defendants that its workaround does not take its activities outside the FDA's purview. The Rule itself provides notice in clear and unambiguous terms.

"Just as everyone is charged with knowledge of the United States Statutes at Large, Congress has provided that the

appearance of rules and regulations in the Federal Register gives legal notice of their contents." Duncan v. Peninger, 624 F.2d 486, (4th Cir. 1980) (quoting Federal Crop Ins. Corp. v. Merrill, 332 U.S. 380, 384-85 (1947)).

It is undisputed that defendants' flavoring blends are to be used with a tobacco product. See ECF No. 11-2 at 15 ("Once the customer orders and purchases the nicotine and e-juice, the products are later blended by the customer. Retail employees only provide verbal instructions to the customer on properly mixing the nicotine with the flavored e-juice. The firm does not have or provide written instructions. Customers are informed to empty all of the nicotine into their bottle of flavored e-juice and shake the combined bottle to mix. The customer will then add the e-liquid into the tank of their vaping device. Mr. Jeffrey stated that they initially instruct new customers on this method, but the established customers who have been vaping for some time know and understand how to properly mix the components together. Mr. Jeffrey stated that his customers are informed of and know that they must mix the nicotine with the e-juice blend and that they cannot vape the nicotine in its purchased form alone."). Therefore, they are a component or part of a tobacco product and subject to regulation.

C.

The cases defendants cite in support of their argument that they did not receive notice sufficient to satisfy due process do not aid their position. To be sure, "a party must receive fair notice before being deprived of property." United States v. Hoechst Celanese Corp., 128 F.3d 216, 224 (4th Cir. 1997).

> The Due Process Clause of the Fifth Amendment protects parties from being deprived of property without fair notice. U.S. Const. amend. V; United States v. Hoechst Celanese Corp., 128 F.3d 216, 224 (4th Cir. 1997). For this reason, and in light of the "quasi-criminal" nature of civil penalties, we have long recognized that "parties subject to . . . administrative sanctions are entitled to . . . 'clear notice'" of what conduct is proscribed by a regulation before being subject to monetary penalties for a particular violation. Id. (quoting First Am. Bank of Va. v. Dole, 763 F.2d 644, 651 n.6 (4th Cir. 1985)). Whether a sanctioned party had adequate notice of a particular violation turns on the "relevant facts of each case." Id. (citing United States v. Bennett, 984 F.2d 597, 605 (4th Cir. 1993)).

Consol Buchanan Mining Co., LLC v. Secretary of Labor, 841 F.3d 642, 648-49 (4th Cir. 2016). "To provide notice that satisfies constitutional due process, a regulation must give the person of ordinary intelligence a reasonable opportunity to know what is prohibited so that he may act accordingly." United States v. Ancient Coin Collectors Guild, 899 F.3d 295, 322 (4th Cir. 2018) (cleaned up). "[A] regulation provides fair notice if it is 'reasonably comprehensible to people of good faith.'" Id. at

321-22 (quoting Gen. Elec. Co. v. Envtl. Prot. Agency, 53 F.3d 1324, 1330 (D.C. Cir. 1995)). In Ancient Coin Collectors, the Fourth Circuit Court of Appeals summarized the Hoechst Celanese decision which explained how a fair notice argument could be applied to regulatory provisions. See id. at 322.

> In the context of regulatory provisions, our 1997 decision in Hoechst Celanese is instructive. The EPA had pursued an enforcement action against an industrial plant for violations of regulations promulgated under the Clean Air Act. The regulations imposed emissions standards and reporting requirements on emitters of a pollutant called benzene. The plant owner, Hoechst, interposed a due process claim to the enforcement action. Hoechst contended that it was not subject to the EPA enforcement order because the EPA regulations failed to provide fair notice that Hoechst's plant had to comply with the benzene regulations.
>
> Our Hoechst Celanese decision engaged in a fact-intensive inquiry, assessing the due process defense and explaining that it was "crucial to examine the particular situation of the defendant, and whether it lacked reasonable notice." See 128 F.3d at 224. That inquiry revealed that, for five years after the benzene regulations went into effect, Hoechst had not been fairly apprised of its obligations under the regulations. We emphasized that the benzene regulations were ambiguous and potentially supported Hoechst's interpretation of the contested regulations. More importantly, we recognized that Hoechst officials had contacted the state regulators enforcing the benzene regulations seeking to determine whether they were in compliance, and that Hoechst had actually received an inaccurate response. We thus concluded that Hoechst could not be liable for its failure to comply with the benzene regulations during the period it lacked fair notice of its regulatory obligations.
>
> The Hoechst Celanese inquiry, however, also revealed that five years after the benzene regulations went into effect, the EPA reached out to Hoechst and

> informed its officials how the EPA actually interpreted the regulations. That EPA communication provided "unequivocal, actual notice as to how the regulation[s] pertained to that plant's operations." See 128 F.3d at 229. Because Hoechst "well understood" that its interpretation and application of the benzene regulations conflicted with the EPA's interpretations, Hoechst was civilly liable for its post-notification violations of the benzene regulations. Id. at 227-30.

Id.

In the instant case, the government is not seeking monetary penalties or otherwise seeking to deprive defendants of property. Therefore, this case is easily distinguishable from most of defendants' cases. Nor is the statute or regulation ambiguous. None of the cases cited by defendants compel a finding that defendants did not have the required notice.

D.

Essentially what defendants ask the court to do is to prohibit the government from enforcing the Act because FDA employees did not tell Jeffrey at the inspection that what he was doing was prohibited. But to the extent that defendants argue the government should be estopped from enforcing the Act because of the investigator's actions during the inspection, that argument fails. "[W]inning an estoppel argument against the government is a tough business." Wade Pediatrics v. Dep't of Health and Human Servs., 567 F.3d 1202, 1206 (10th Cir.

2008); see Office of Pers. Mgmt. v. Richmond, 496 U.S. 414, 422 (1990) (noting that the Supreme Court had, to date, "reversed every finding of estoppel that [it had] reviewed"). "Courts are parsimonious about estoppel claims against the government for good reason: 'When the government is unable to enforce the law because the conduct of its agents has given rise to an estoppel, the interest of the citizenry as a whole in obedience to the rule of law is undermined.' . . . The public should not have to suffer, the reasoning goes, because of a bureaucratic bungle." Wade Pediatrics, 567 F.3d at 1206 (quoting Heckler v. Cmty. Health Servs. of Crawford Cty., Inc., 467 U.S. 51, 60 (1984)).

The Supreme Court has made clear "that estoppel may only be justified, if ever, in the presence of affirmative misconduct by government agents." Achampoma v. Bd. of Immigration Appeals, Case No. 1:16-cv-00668-GBL-MSN, 2016 WL 8732313, at *6 (E.D. Va. Dec. 2, 2016) (citing Dawkins v. Witt, 318 F.3d 606, 611 (4th Cir. 2003)). "Mere negligent conduct on the part of federal officials does not amount to 'affirmative misconduct' as required to sustain a claim of equitable estoppel." Id.; see also United States v. Exxon Corp., 561 F. Supp. 816, 847 (D.D.C. 1983) (acknowledging "the longstanding principle that the courts look with extreme disfavor upon estoppel of the government on the basis of unauthorized statements by its employees").

Even crediting Jeffrey's assertion that McNew told him that what he was doing did not violate the law, that negligent misstatement does not amount to affirmative misconduct. "The Government is simply not bound by the negligent, unauthorized acts of its agents. Federal law is clear that estoppel is rarely, if ever, a valid defense against the Government absent proof of some affirmative misconduct by a Government agent, and estoppel against the Government cannot be premised on oral representations." United States v. Vanhorn, 20 F.3d 104, 112 n.19 (4th Cir. 1994); see also S&M Inv. Co. v. Tahoe Regional Planning Agency, 911 F.2d 324, 329 (9th Cir. 1990) (holding that a party seeking to invoke estoppel against the government could not establish affirmative misconduct on the government's part where the "conduct at issue involve[d] one oral misstatement by a low-level government employee"). As the S&M court explained, "[i]n dealing with the government, an individual is charged with knowing government statutes and regulations and assumes the risk 'that government agents may exceed their authority and provide misinformation.'" Id. (quoting Lavin v. Marsh, 644 F.2d 1378, 1383 (9th Cir. 1981)); see also Wade Pediatrics, 567 F.3d at 1206 (mere "erroneous advice" does not satisfy burden to show affirmative misconduct on the part of government); Wagner v. Dir., Fed. Emergency Mgmt. Agency, 847 F.2d 515, 519 (9th Cir. 1988) (noting "there is always a risk that misinformed agency

employees may err in interpreting statutes and regulations"); cf. Schweiker v. Hansen, 450 U.S. 785, 788-90 (1981) (holding there was no affirmative misconduct when a field representative of the Social Security Administration erroneously informed a claimant that she was ineligible for benefits).

In short, any erroneous advice/statement/oversight by FDA investigators during the inspection is not grounds to exempt defendants from following the law.[4]

E.

21 U.S.C. § 331 prohibits any act that causes a tobacco product to become adulterated or misbranded while held for sale after shipment of one or more of their component parts in interstate commerce. "A tobacco product shall be deemed to be adulterated if . . . it is required . . . to have premarket review and does not have an order in effect." 21 U.S.C. § 387b(6)(A). "A tobacco product shall be deemed to be misbranded . . . [if] a notice or other information respecting it was not provided as required" under the SE pathway or SE exemption pathway, including an SE report or an abbreviated report." 21 U.S.C. § 387c(a)(6).

[4] Defendants argued that summary judgment was premature because they needed discovery to support their argument concerning a lack of notice. As the court explained above, that argument is without merit and, therefore, the requested discovery would not create a genuine issue of material fact.

In its motion for summary judgment, the United States argued that defendants' ENDS products are adulterated and misbranded. Defendants did not respond to this argument. Their failure to do so is a concession that plaintiff is entitled to summary judgment on that claim. See Butler v. United States, No. 5:20-CV-00480-BO, 2022 WL 5239520, at *1 (E.D.N.C. Aug. 3, 2022) (noting that a failure to address the arguments presented by moving party, amounts to a concession that summary judgment is appropriate on that issue); Intercarrier Commc'ns, LLC v. Kik Interactive, Inc., No. 3:12-cv-771, 2013 WL 4061259, at *1 (E.D. Va. Aug. 9, 2013) (concluding that where party fails to respond to an argument it is "effectively conceding" the argument).

Even without defendants' concession, however, the United States has demonstrated that there are no disputed issues of material fact concerning this claim. In order to prevail, plaintiff had to show that defendants' ENDS products are 1) tobacco products and 2) new tobacco products, that 3) lack the required FDA authorization (adulterated) or the required SE or abbreviated report (misbranded), and that 4) defendants held the products for sale after shipment of their components in interstate commerce.

As explained above, defendants' ENDS products are tobacco products. And, because it is undisputed that there were not "commercially marketed in the United States as of February 15,

2007," they are "new tobacco products." In addition, "Defendants have not submitted marketing applications for any of Defendants' ENDS products, and Defendants have not received any found-exempt orders, SE orders, or MGOs from FDA for any of Defendants' ENDS products." Ibarra-Pratt Decl. at ¶ 20. Finally, as for the interstate commerce element, the VG and PG that defendants use to make their blends comes from Ohio. See ECF No. 11-2 at 13.

F.

Pursuant to 21 U.S.C. § 387e(b), "[o]n or before December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person." Additionally, every person who registers under this section "shall, at the time of registration . . . file with the Secretary a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution. . . ." 21 U.S.C. § 387e(i). Under the statute, "[t]he term 'manufacture, preparation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any product package in furtherance of the distribution of the tobacco product from the

original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user." 21 U.S.C. § 387e(a)(1). 21 U.S.C. § 331(q)(2) makes it illegal to submit a required report concerning a "tobacco product . . . that is false or misleading in any material respect."

The FDA maintained that defendants violated 21 U.S.C. § 331(q)(2) when it changed its tobacco manufacturing status to "inactive" and that it was entitled to summary judgment in its favor. As noted above, on September 20, 2018, defendants registered Soul Vapor as an owner or operator of a single domestic establishment. See Ibarra-Pratt Decl. at ¶ 22 and Exhibit 3 thereto. On September 20, 2021, in their annual registration to FDA, defendants changed the activity status for Soul Vapor from "active" to "inactive" and reported as a reason that the establishment was "[o]ut of business." Ibarra-Pratt Decl. at ¶ 23 and Exhibit 4 thereto. However, during the FDA's March 2022 inspection, FDA's investigators observed that, contrary to the September 20, 2021, registration, that defendants were in fact engaged in the manufacture of tobacco products. See Ibarra-Pratt Decl. at ¶ 24. Given that Soul Vapor was not inactive, the September 2021 registration was false and misleading.

For their part, defendants do not deny changing the registration status. See Jeffrey Decl. at ¶ 19. According to Jeffrey:

> In September 2021, I logged into the FDA's registration system to update our status based on our changed operations and product offerings. From what I recall, the only options are stating that you are in business or out of business. I designated Soul Vapor as inactive, because we are not active in a way captured by the law or FDA regulations, which only extend to tobacco product manufacturers/processers as defined in the statute. At this point we are just a vape shop that is not engaged in manufacturing regulated products.

Jeffrey Decl. at ¶ 19. And, in their brief, defendants concede "[t]here is no question that Defendants changed the registration status of Soul Vapor with the FDA[.]" ECF No. 26 at 11. They maintain however, the government cannot show the change is misleading. See id. Defendants are wrong.

During the March 2022 inspection, Investigator McNew "documented that Defendants manufacture, sell, and distribute ENDS products, including finished e-liquid products, at and from Defendants' establishment." McNew Decl. at ¶ 9. McNew stated that those "manufacturing activities included mixing, bottling, and labeling their ENDS products." Id. McNew elaborated:

- During the March 2022 inspection, Soul Vapor was not manufacturing ENDS products at Defendants' establishment. However, I observed evidence of ENDS product manufacturing at Defendants' establishment, including nicotine, flavorings, bottles, labels, and equipment to manufacture ENDS products. In

> addition, Mr. Jeffrey told me that Soul Vapor currently manufactures ENDS products.
>
> - During the March 2022 inspection, Mr. Jeffrey stated that Defendants' ENDS product manufacturing includes: bottling bulk liquid nicotine at varying concentrations into 10mL bottles, and, separately mixing flavoring(s) with propylene glycol ("PG") and vegetable glycerin ("VG"), and packaging the resulting flavoring/PG/VG blend into 10mL, 30mL, or 120mL bottle.

McNew Decl. at ¶¶ 11-12. In his Inspection Report, McNew made the following observations:

> The current inspection revealed that the firm inactivated its registration with FDA under its previous tobacco manufacturing status as of 9/20/21, and listed being "out-of-business" (OOB). The firm was found to be in business as a retail vape shop providing raw nicotine solution and e-juice components at the retail level. The firm owner, Mr. Aurelius Jeffrey, stated that he inactivated his tobacco registration because he believes his current operations do not meet the legal definition of tobacco manufacturing. The firm's current operation style consists of selling retail customers repackaged tobacco nicotine in 10mL bottles separate from bottles of propylene glycol (PG), vegetable glycerin (VG) and flavors (e-juice).

ECF No. 11-2 at 9-10.

McNew elaborated on Soul Vapor's operations as it concerned nicotine. He noted that Jeffrey admitted he purchased nicotine which was the "repackaged into 10mL bottles on-site without further dilution. Id. at 12. "To fill a nicotine order, the (raw nicotine solution is transferred into a 16 oz. squeeze bottle for easier handling and order fulfillment. When a customer orders a specific nicotine strength, an employee fills

the 10mL bottle scale and weighs out the nicotine to the strength level required according to their conversion factor." Id. at 17.

As the court explained earlier, defendants' PG/VG flavoring blends are tobacco products under the Act. Furthermore, 21 U.S.C. § 387e(b) would also capture defendants' activities in repackaging nicotine. See 21 U.S.C. § 387e(a)(1) ("manufacture, preparation, compounding, or processing" includes repackaging). It is therefore clear that, as of the March 2022 inspection, defendants were actively engaged in the manufacture, preparation, compounding, or processing of tobacco products. For this reason, defendants' registration was false or misleading within the meaning of the statute.

G.

"An injunction is a matter of equitable discretion; it does not follow from success on the merits as a matter of course." Winter v. Nat. Res. Defense Council, Inc., 555 U.S. 7, 32 (2008). "[A] federal district court has wide discretion to fashion appropriate injunctive relief in a particular case." Richmond Tenants Org., Inc. v. Kemp, 956 F.2d 1300, 1308 (4th Cir. 1992). "That discretion must be balanced against the tenet that a court ordinarily should craft a remedy that is 'no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs.'" American Coll. of Obstetricians and

Gynecologists v. FDA, 472 F. Supp.3d 183, 229-30 (D. Md. 2020) (quoting Califano v. Yamasaki, 442 U.S. 682, 702 (1979)).

"The FDCA authorizes district courts to provide injunctive relief to restrain violations of the statute. 21 U.S.C. § 332(a)." United States v. Confidence, U.S.A., Inc., 19-CV-3073 (ERK) (SIL), 2021 WL 293525, at *8 (E.D.N.Y. Jan. 28, 2021). "Injunctive relief is appropriate when the government has demonstrated that defendants have violated [the FDCA] and that there is some reasonable likelihood that the violations may recur." Id. (internal citation and quotation omitted). "[T]he fact that an injunction may put a party out of business is irrelevant, for there is vested interest in a business activity found to be illegal." United States v. N.Y. Fish, Inc., 10 F. Supp.3d 355, 380 (E.D.N.Y. 2014) (internal quotation omitted). Nevertheless, there are limits to injunctive relief, which should be narrowly tailored to fit specific legal violations." Id.

Defendants' history of past violations as well as the record in this case show that there is some reasonable likelihood that violations may recur. Throughout the course of this litigation, defendants have maintained that their business activities do not fall under the TCA. This court has concluded otherwise. Therefore, an injunction is needed to ensure future compliance with the Act.

However, the court agrees with defendants that certain aspects of the government's proposed injunction go too far. Certain provisions also appear to be unnecessary under the circumstances of this case. For example, the United States seeks to prohibit defendants from selling products that are lawfully marketed and sold in the United States unless and until the FDA inspects defendants' business.[5] The proposed injunction provides no timeline for this inspection. The government has failed to show that 3(C)'s inspection provision is warranted. Although an inspection might be merited, the court does not believe that defendants should be prohibited from selling FDA-approved ENDS products until it happens.

There is nothing in the record to indicate that defendants plan to continue to manufacture new tobacco products, as Jeffrey indicated on multiple occasions that he did not intend to seek premarket approval for the Soul Vapor products. Therefore, there should be no sales of Soul Vapor-manufactured products at

[5] The court is referring to those ENDS products that have received FDA approval. See ECF No. 43-2. Both in his brief and at the hearing, counsel for defendants referred to a set of products "that are otherwise legally sold either under FDA's enforcement discretion (afforded in limited circumstances for products that are either under review by FDA or where a marketing denial order has been rescinded by the agency itself) or pursuant to a court order vacating a denial order for the product. See ECF No. 42. However, upon questioning from the court, counsel for defendants was unable to provide a way to determine the universe of those products, making it impossible to exempt them from the injunction's terms.

all. For this reason, the provision of the proposed injunction providing for a written destruction plan appear appropriate. An appropriate injunction will be entered.

IV. Conclusion

For the reasons stated above, the court granted plaintiff's motion for summary judgment and entered the permanent injunction entered this day.

The Clerk is directed to send a copy of this Memorandum Opinion to counsel of record.

IT IS SO ORDERED this 1st day of July, 2024.

ENTER:

David A. Faber
Senior United States District Judge